K132935
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FEB 21 2014

Section 5

510(k) Summary

Date Prepared: September 12, 2013

Submitter: Siemens Medical Solutions USA, Inc.
Radiation Oncology
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Proprietary Name: *syngo*® RT Therapist Workspace, v4.3.1
And the optional 3rd party OIS Connectivity System

Common Name: Accessory To; Medical Charged-Particle Radiation Therapy System

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

Product	510(k) Clearance / Date	Claim of Equivalence for:
COHERENCE™ RT Therapist Connect update to Sys_32A (RTTC v2.3) with Control Console 9.2.18 and 11.0.212 supporting 3rd party OIS, V&R called ARIA and Varian Treatment[8] and third party TPS and PACs systems	K123812 / March 01, 2013	*Syngo*® RT Therapist with software version 4.3.1, with Control Console v13, an update to Sys_VC10C supporting 3rd party OIS, V&R called ARIA and Varian Treatment[9] and third party TPS and PACs systems
ARTISTE™ Solution with SYS-VC10A for the *syngo*® RT Therapist (RTT v4.3, CC 13) supporting 3rd party OIS, V&R	K121295 / June 12, 2012	*Syngo*® RT Therapist with software version 4.3.1, with Control Console v13, an update to Sys_VC10C supporting 3rd party OIS, V&R called ARIA and Varian

[8] ARIA OIS and Varian Treatment V&R systems are manufactured by Varian Medical Systems.
[9] ARIA OIS and Varian Treatment V&R systems are manufactured by Varian Medical Systems.

called MOSAIQ and Sequencer V&R[10] and third party TPS and PACs systems.		Treatment[11] and third party TPS and PACs systems
syngo® RT Therapist Connect (RTT v4.2, CC 12) (ARTISTE, ONCOR and PRIMUS Linacs) supporting 3rd party OIS, V&R called MOSAIQ and Sequencer V&R[12] and third party TPS and PACs systems	K103606 / April15, 2011	*Syngo*® RT Therapist with software version 4.3.1, with Control Console v13, an update to Sys_VC10C supporting 3rd party OIS, V&R called ARIA and Varian Treatment[13] and third party TPS and PACs systems.

The update to the *syngo*® RT Therapist Workspace, v4.3.1 as described in this premarket notification has the same intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary

syngo® RT Therapist Workspace, v4.3.1

Technological Characteristics:

The *syngo*® RT Therapist Workspace v4.3.1 release is intended to update customers with the currently released *syngo*® RT Therapist Workspace software with version v4.3 for ARTISTE, ONCOR & PRIMUS Linear Accelerator systems. The technological characteristics and the fundamental technology of the *syngo*® RT Therapist Workspace v4.3.1 remain unchanged from the currently cleared products.

The *syngo*® Software Architecture:

The *syngo*® RT Therapist software utilizes the proprietary *syngo*® software architecture design that provides a method of delivering customized software applications based on the modality as clinically supporting packages. SIEMENS utilizes, as part of the Oncology clinical focus package, multiple *syngo*® software applications for patient set-up and position verification, treatment localization, treatment verification, portal imaging as well as data processing, image reformatting, display and printing. The currently cleared *syngo*® based software products also includes an array of image-oriented software tools, support for DICOM connectivity, Siemens Remote Service [SRS], and virus protection features. Note: *syngo*® is both a proprietary software architecture and a market brand.

This update is intended to be backwards compatible to upgrade the currently cleared ONCOR and PRIMUS family of medical linear accelerators and their Control Consoles (v9.2+ & v11.0, v12), the COHERENCE™ RT Therapist (v2.3) workspace (K123812). Additionally, the ARTISTE

[10] MOSAIQ OIS and Sequencer V&R systems are manufactured by IMPAC Medical / Elekta AB.
[11] ARIA OIS and Varian Treatment V&R systems are manufactured by Varian Medical Systems.
[12] MOSAIQ OIS and Sequencer V&R systems are manufactured by IMPAC Medical / Elekta AB.
[13] ARIA OIS and Varian Treatment V&R systems are manufactured by Varian Medical Systems.

Solution with the *syngo*® RTT v4.1x and v4.2x (K103606) can also be upgraded. These previous versions can be migrated to the current release (*syngo*® RTT. v4.3) and Control Console 13.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Refer to Section 21 for the Risk Management documentation.

Intended Use:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The *syngo*® RT Therapist workspace is a component of the linear accelerator system and is based on the *syngo*® architecture. The *syngo*® RT Therapist workspace contains software applications to support patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The syngo® RT Therapist Workspace v4.3.1 can be interfaced with third party devices conforming to the DICOM Standard.

Substantial Equivalence:

The Substantial Equivalence comparison chart demonstrates the comparison of the technological characteristics of the *syngo*® RT Therapist Workspace update to the currently cleared predicate devices.

The *syngo*® RT Therapist Workspace v4.3.1 (project Sys_VC10C) does not change the intended use of the original ARTISTE™ Solution with the *syngo*® RT Therapist Workspace v4.3 (project Sys_VC10A) or the previously cleared ONCOR™ or PRIMUS™ Siemens branded Linear Accelerator Systems.

Bench Testing:

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the software update v4.3.1 for the RT Therapist and regression testing the Control Console version 13.

All testable requirements in the System Requirements Specifications (SRS) and Component Requirements (CRS) for the Sys_VC10C project, and additionally the specific requirements for the implementation of the third party OIS have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process (PDP).

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Concept.

Non-Clinical Test Results:

Validation of the *syngo*® RT Therapist Workspace v4.3.1, implementation of the optional third party OIS and regression testing with Control Consoles 13 has been performed at the System test level on production prototype devices by appropriately trained and knowledgeable test personnel. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans.

Testing to Consensus Standards:

The *syngo*® RT Therapist Workspace v4.3.1 and the Control Console 13 supporting the third party OIS and V&R implementation have been tested to meet the requirements for conformity (where applicable) to multiple industry standards.

Refer to Sections 9 and 17 for this content.

Substantial Equivalence to Predicates:

The verification testing to the System requirements for the *syngo*® RT Therapist workspace, validation of the intended use, and the regression testing to the existing *syngo*® RT Therapist software and Control Console functional requirements, is intended to support the claim of substantial equivalence to the following predicates:

- The COHERENCE™ RT Therapist Connect v2.3 with Control Consoles 9.2.18 and 11.0.212 supporting 3rd party OIS & V&R (ARIA and Varian Treatment[14] System) and third party TPS and PACs systems (K123812).
- The ARTISTE™ Solution with SYS-VC10A for the *syngo*® RT Therapist (RTT v4.3, CC 13) supporting 3rd party OIS & V&R (MOSAIQ and Sequencer V&R[15]) and third party TPS and PACs systems. (K121295).
- The *syngo*® RT Therapist Connect (RTT v4.2, CC 12) (ARTISTE, ONCOR and PRIMUS Linacs) supporting 3rd party OIS & V&R (MOSAIQ and Sequencer V&R[16]) and third party TPS and PACs systems (K103606).

[14] ARIA OIS and Varian Treatment V&R systems are manufactured by Varian Medical Systems.
[15] MOSAIQ OIS and Sequencer V&R systems are manufactured by IMPAC Medical / Elekta AB.
[16] MOSAIQ OIS and Sequencer V&R systems are manufactured by IMPAC Medical / Elekta AB.

Summary:

In summary, it is SIEMENS' opinion that the *syngo*® RT Therapist Workspace update to v4.3.1 including the optional 3rd party OIS Connectivity system (ARIA OIS), does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

SIEMENS MEDICAL SOLUTIONS USA, INC.
% CHRISTINE DUNBAR
SENIOR MANAGER, REGULATORY AFFAIRS
757A ARNOLD DRIVE
MARTINEZ CA 94553

Re: K132935
Trade/Device Name: syngo® RT Therapist Workspace, v4.3.1 & optional 3rd party OIS Connectivity System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 4, 2013
Received: October 7, 2013

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

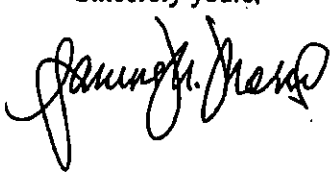
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132935

Device Name
syngo RT Therapist Workspace, v4.3.1

Indications for Use *(Describe)*

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-ray photon and electron radiation for the therapeutic treatment of cancer.

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The syngo® RT Therapist Workspace v4.3.1, can be interfaced with third party devices conforming to the DICOM Standard.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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